

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Kurachi *et al.*  
Serial No.: 10/018,392 Group No.: 1633  
Filed: 08/21/2002 Examiner: Q. Nguyen  
Entitled: **NUCLEOTIDE SEQUENCES FOR GENE REGULATION AND  
METHODS OF USE THEREOF**

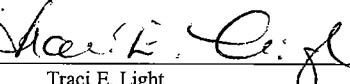
**AMENDMENT AND RESPONSE TO  
THE RESTRICTION REQUIREMENT OF  
FEBRUARY 19, 2008 OFFICE ACTION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Patent & Trademark Office, via EFS.

Dated: April 17, 2008

By:   
Traci E. Light

Sir:

This is responsive to the Office Action mailed on 2/19/08, a response to which is due by 3/19/08. Since the response is timely filed, a petition and fee for an extension of time are not required.

**1. THE RESTRICTION**

The Examiner required restriction between the following species of a generic invention:

- a. SEQ ID NO: 3,
- b. SEQ ID NO: 91,
- c. SEQ ID NO: 93,
- d. SEQ ID NO: 3 and SEQ ID NO: 91,
- e. SEQ ID NO: 3 and SEQ ID NO: 93,
- f. SEQ ID NO: 91 and SEQ ID NO: 93,
- g. SEQ ID NO: 3 and SEQ ID NO: 91 and SEQ ID NO: 93.

Applicant notes the Examiner's remark that the generic claims are 1-2, 13, 15, 21, 23, and 28-30,<sup>1</sup> and that "the claims shall be restricted if no generic claim is finally held to be allowable."<sup>2</sup>

## 2. **ELECTION**

Applicant elects the species of SEQ ID NO: 3, with traverse. While portions of SEQ ID NO:3 are patentably distinct, there is nonetheless a technical relationship and even a sharing of a special technical feature (disclosed below). Furthermore, there is no undue search burden.

## 3. **TRAVERSAL OF RESTRICTION**

Applicant traverses the restriction requirement because the Examiner has failed to demonstrate a) an undue search burden, and b) lack of unity of invention under PCT Rule 13.1. Under PCT Rule 13.1, unity of invention exists

"when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

The Examiner stated that "each recited SEQ ID NO is different one from the others, as well as the various combinations of the differently recited SEQ ID NOs.; and each SEQ ID NO. is considered to be a specific technical feature. Therefore they lack a common unity of invention."<sup>3</sup>

This is a conclusory statement. It neglects to consider that the "**corresponding special technical feature**" between the sequences is that they each contain the 102-bp stem-loop forming sequence (SEQ ID NO:91). In other words, SEQ ID NO: 91 is a 102-bp stem-loop forming sequence that is contained within the 154-bp SEQ ID NO:93 (AE3'), which in turn is contained within the 1273-nt SEQ ID NO:3 (AE3'). This is described in the Specification as follows:

"The present invention also provides the 1273-nucleotide nucleic acid sequence (SEQ ID NO:3) (Figure 13) of AE3' which corresponds to the sequence from 34,383 to 35,655 of GenBank accession number K02402, and which corresponds to the sequence from 31,418 to 32,690 of Figure 8 when in relation to the hFIX

---

1 Office Action, page 3, penultimate paragraph.

2 Office Action, page 2, last paragraph.

3 Office Action, page 4, first paragraph.

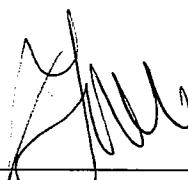
start codon (ATG) in which the adenine is designated as position +30.”<sup>4</sup>

“The invention further provides the nucleotide sequence AE3” which is a preferred portion of AE3'. AE3” [5'-ttgggg gaaaagttc ttcagagag ttaagttatt ttatatatat aatatatata taaaatatataat aatatacaat ataaatatataat agtgtgtgtg tgtatgcgtg tgtgtagaca cacacgcata cacacatata atggaagcaa taagccat-3'; (SEQ ID NO:93)] is the 154-nucleotide nucleic acid sequence from 35,075 to 35,228 of GenBank accession number K02402, which corresponds to the sequence from 32,110 to 32,263 of Figure 8 when in relation to the hFIX start codon (ATG) in which the adenine is designated as position +30. AE3” contains a 102-bp stem-loop forming sequence (SEQ ID NO:91).”<sup>2</sup>

Importantly also, the Examiner has failed to consider that the above discussed “special technical feature” contributes to the age regulatory activity of SEQ ID NOs: 3, 91, and 93, which **defines a contribution which each of the claimed inventions, as a whole, makes over the prior art.**

Since the Examiner did not establish a) an undue search burden, and b) lack of unity in accordance with the PCT Rule 13.1, Applicant respectfully requests withdrawal of the restriction requirement.

Dated: April 17, 2008

  
Peter G. Carroll  
Registration No. 32,837

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
(617) 252-3353 (415) 904-6500

4 Specification, page 28, lines 14-18.  
5 Specification, page 36, lines 3-10.